

REMARKS

Claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-39 are pending in this application. According to the Office Action Summary, claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-39 are rejected, claim 34 is allowed, and claim 35 is objected to. However, after reading the specific rejections in the Office Action, applicant believes that there may be an error in line 6 of the Office Action Summary (which includes claim 34 in the list of rejected claims) as this list is inconsistent with line 5 of the Office Action Summary (which states that claim 34 is allowed), and since there are no objections to or rejections of claim 34.

In the Advisory Action mailed December 28, 2006, the Examiner did not enter the amendment of December 7, 2006, asserting that deletion of the phrase “diagnosed as not having the disease” from claims 1 and 23 would result in undue new considerations. (See pages 1 and 2 of the Advisory Action.). Although applicants do not agree, this phrase (which was added to claims 1, 23 and 37 by a Response filed by Applicants on September 6, 2006) has been added back to claims 1 and 23, as well as to claim 37, which was not mentioned in the Advisory Action, in order to expedite prosecution of the application.

By the present amendment, the specification is amended to provide the correct filing date of the second-filed provisional application, namely US Provisional Application 60/283,432, to which the present application properly claims benefit. (See the filing receipts for (a) the present application, (b) US Provisional Application 60/259,340 (hereinafter “Provisional ‘340”), and (c) US Provisional Application 60/283,432 (hereinafter “Provisional ‘432”) , copies of which are all attached hereto for the Examiner’s convenience. See also 37 CFR 1.78, a copy of which appears on page 1 of the document marked “Appendix”, which is attached hereto for the Examiner’s convenience, and which states that a non-provisional application can claim benefit to more than one provisional application.) Paragraph 1 has also been amended to use the language suggested in MPEP 201.11 (B) for claiming benefit of the filing date of a provisional application. (See MPEP 201.11, which also appears on page 1 of the attached Appendix.) By the present amendment, claims 1, 2, 23, 26, 28, 29, 31, 32, 33, 35, 36, 37, and 38 are amended for clarity. The amendments are fully supported by the application and add no new matter.

Applicant thanks the Examiner for the telephone conference of December 1, 2006, during which the §102/103 rejection based on the absence in Provisional ‘432 of a priority claim to or

more specifically “an incorporation by reference” of Provisional ‘340 (see Page 5 of the Office Action) was discussed, and the telephone conference of December 4, 2006, during which the meaning of the term “risk of having” was discussed.

In view of the above-described amendments and following remarks, reconsideration of claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-33 and 35-39 is respectfully requested.

Objections

Claims 2, 28, 32, 35, and 38 are objected to under 37 CFR 1.75(c) as being of improper dependent form. The base claims for claim 2, namely claim 1, and the base claim for claim 35, namely claim 34, recite that the blood leukocytes are “selected from the group consisting of neutrophils and monocytes, or any combination thereof”. The base claim for claims 28 and 32, namely claim 23, and the base claim for claim 38, namely claim 37, recite that the blood leukocytes are selected “from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereof”. To ensure that the rejected claims are not of broader scope than their base claims, claims 2, 28, 32, 35, and 38 have been amended to no longer recite “one or more populations of leukocytes”. In addition, the rejected claims have also been amended for clarity to recite that it is “said blood leukocytes”, i.e., the blood leukocytes recited in the base claim, that are being tested in the assay. Applicants submit that the amendments overcome the objections. If the Examiner disagrees, Applicants request that he call Pamela A. Docherty at (216) 622-8416 to discuss further amendments.

§ 112 Rejections

Claims 1-5, 7-10, 23, 25, 26, 28, 29, and 31-33. and 35-39 are rejected under 35 USC § 112, second paragraph “as being indefinite.”

With respect to the term “risk of having” that appears in independent claims 1, 23, 31, and 33 of the present application, this term means that a subject with high levels of MPO has a high probability of having atherosclerotic cardiovascular disease (CVD). Thus, the methods recited in claims 1, 23, 31, and 33, and the claims that depend therefrom, are prognostic methods as opposed to the “gold-standard” diagnostic test for atherosclerotic CVD, i.e., angiography.

Claims 23 and 37 have been amended to remove the second inclusion of “sub-

populations of neutrophils. Claims 23 and 26 have been amended for clarity to identify the bodily samples that are used to determine levels of MPO and to ensure that the bodily sample of the “determining” clause and the bodily sample of the “wherein” clause are consistent and of the same scope.. Applicants submit that the amendments to claims 23, 26, and 37 overcome the §112 rejection. If the Examiner disagrees, Applicants request that he call Pamela A. Docherty, at (216) 622-8416 to discuss further amendments.

§102/103 Rejections

Claims 23, 26, 29, 37, and 39 are rejected under 35 USC §102(a) as anticipated by or alternatively under 35 U.S.C. 103(a) as being obvious over Zhang et al (JAMA, 286, 2136) (hereinafter Zhang et al). As stated in the Office Action:

The reference has a 102(a) date because the instant claims are only accorded benefit of the instant filing date of 1/3/02.....Claims are deemed broader because of at least the following features:

- 1) the nature of the controls.There is no teaching of controls from the “general population” and there is no teaching of any “select population of controls” other than “healthy” controls.” In amended claim 26, the nature of the “control subjects” has not been changed so that they are of the same scope as the “healthy controls” of Prov. Applic 60/283,432.
- 2) the nature of the sample. In the ‘432 application the “leucocytes are limited to neutrophils or sub-populations of monocytes or any “combinations that would include these. In amended claim 23, and in new claim 37 , applicant has included these sub-populations. Applicant has urged that earlier filed US Prov. Applic. 60/259,340 teaches such sub-populations at p. 9. **While the examiner concurs that this teaching is present**, it is not effective, because later filed Prov. Applic. 60/283,432 did not incorporate Prov. Applic. 60/259,340 by reference. Applicant wants to rely upon the disclosure of Prov. Applic. 60/259, 340 in order to obtain an effective filing date of 1/2/01 for overcoming the Zhang et al reference; it is to be noted, however, that this reference fails to disclose blood, serum, or plasma examples. Thus, Prov. Applic 60/529,340 would fail to support instant claims encompassing the use of blood serum or plasma samples. (See pages 4 and 5 of the Office Action. Emphasis added.)

The present application properly claims benefit to two provisional applications, namely US Provisional Application 60/259,340 filed Jan. 2, 2001 (hereinafter “Provisional ‘340”) and U.S. Provisional Application 60/283,432, filed April 12, 2001 (hereinafter “Provisional ‘432”). Thus, with respect to the embodiments disclosed in Provisional ‘340 and Provisional ‘432, the

present application has two effective filing dates, both of which antedate Zhang et al.

According to 37 CFR 1.78, which is shown on page 1 of the attached Appendix, a later-filed non-provisional application can claim the benefit of multiple prior-filed provisional applications as long as each prior-filed provisional application names “as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112”. (See 37 CFR 1.78) As noted in the filing receipts that are attached hereto, the present application and Provisional applications ‘340 and ‘432 all name Stanley Hazen and Renliang Zhang as inventors. Moreover, Provisional applications ‘340 and ‘432 both disclose methods of characterizing a test subject’s risk of developing or having atherosclerotic vascular disease by determining levels of MPO mass in blood samples. (See Page 3 of Provisional ‘340 and Provisional ‘432.) In addition, Provisional ‘340 and Provisional ‘432 **both** recite subpopulations of neutrophils and monocytes. (See page 9, line 4 of Provisional ‘340 and page 9, line 8 of ‘Provisional ‘432.) Finally, the present nonprovisional application was filed within 12 months from the filing date of Provisional ‘340 and Provisional ‘432. (See the attached filing receipts.) Thus, the present application can claim the benefit of both of these earlier filed provisional applications.

The priority claims for prior filed provisional applications, which are governed by 35 U.S.C. 119(e), do not have the same requirements as priority claims to prior filed non-provisional applications, which are governed by 35 U.S.C. 120. There is **NO** requirement that a second-filed provisional application, e.g. Provisional ‘432, claim priority to or incorporate by reference a first-filed provisional application, e.g. Provisional ‘340. Indeed, a provisional application cannot claim priority to a previously-filed provisional application. A priority claim in a provisional application is “improper.” As shown on page 3 of the attached appendix, MPEP 201.04(b) states “A provisional application is not entitled to claim priority benefits based on any other application under 35 U.S.C. 119. If applicant attempts to claim the benefit of an earlier U.S. or foreign application in a provisional application, the filing receipt will not reflect the **improper** >benefit or< priority claim”. (Emphasis added.) Moreover, a nonprovisional application that claims priority one or more prior filed provisional applications need not and “should not” specify its relationship with the prior provisional applications. (See MPEP 201.11

as shown on pages 1 and 2 of the attached Appendix.”) With respect to the language of the priority claim in the nonprovisional application, all that is required is that the nonprovisional application provide the number and filing date of each prior provisional application on which the benefit claims are based. (See MPEP 201.11, which also appears on page 1 of the attached Appendix. “When the nonprovisional application is entitled to an earlier U.S. effective filing date of one or more provisional applications under 25 USC 119(e), a statement such as “This application claims the benefit of U.S. Provisional Application NO. 60/_____ filed, and U.S. Provisional Application No. 60_____, filed_____. should appear as the first sentence(s) of the description.”). Thus, the present application properly claims the benefit of both Provisional ‘340 and Provisional ‘432, both of which antedate the publication date of Zhang, i.e., November 7, 2001.

With respect to the controls, amended claims 23, 29, 37, and 39 do not recite a control from the general population or a “select population” Claims 23, 29, 37, and 39 recite control subjects that are the same as the control subjects of claim 26.

With respect to the nature of the sample, the Examiner concurs that Provisional ‘340 teaches sub-populations of neutrophils and subpopulations of monocytes or combinations of these at page 9. (See page 9, line 4 of Provisional ‘340) Provisional ‘432 also teaches subpopulations of monocytes and neutrophils (See page 9, line 8, of Provisional ‘432.) Provisional ‘340 and Provisional ‘432 both teach blood as a sample. (See page 3 of Provisional ‘340 and ‘432.) In addition, Provisional ‘432 teaches serum, and plasma. (See page 2 of Provisional ‘432.). Since the present nonprovisional application is entitled to claim benefit to Provisional ‘340 and Provisional ‘432, both of which antedate Zhang, Applicants submit that §102/103 rejection based on Zhang and the nature of the sample is improper and request that it be withdrawn.

In view of the above-described amendments and remarks, applicants submit that, in addition to allowed claim 34, claims 1-5, 7-10, 23, 25, 26, 28, 29, 31-33, and 35-39 are now in conditions for allowance. Prompt notice of such allowance is respectfully requested. If the Examiner has any questions regarding the amendments or remarks, he is asked to call Pamela A. Docherty, at (216) 622-8416.

Appl. No. 10/039,753

Amdt. dated: January 3, 2007

Response to Final Office Action of November 22, 2006 and Advisory Action of December 28, 2006.

Respectfully submitted,

Date:

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